PATENT COOPERATION TREATY

From the Japan Patent Office

(INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY)

PCT

To: Agent of Applicant
Hajime Takashima

Meiji Yasuda Seimei Osaka Midosuji Building
1-1, Fushimimachi 4-chome,
Chuo-ku Osaka 541-0044 JAPAN

WRITTEN OPINION OF THE INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

(PCT Rule 66)

	Date of mailing *(day/month/year)* 28.6.2005
Applicant's or agent's file reference 09651	**REPLY DUE** within 2 months from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2004/008471	10.06.2004	10.06.2003

International Patent Classification (IPC) Int. Cl[7] G01N33/53

Applicant
DAINIPPON PHARMACEUTICAL CO., LTD.

1. ☒ The written opinion drawn up by the International Searching Authority is regarded a written opinion of the International Preliminary Examining Authority. ☒ yes ☐ no

2. This second report contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d). An extension is granted only when a rational reason exists and schedule is not full.

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or argument, see Rule 66.4*bis*. For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 21.10.2005

Name and mailing address Japan Patent Office (IPEA/JP) 4-3, Kasumigaseki 3-chome Chiyoda-ku, Tokyo 100-8915 Japan	Authorized officer Examiner Shoko Yamamura Telephone No. 03-3581-1101 extension 3252	2J 9217

WRITTEN OPINION OF THE INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

Intern. application No.PCT/JP2004/008471

I. Basis of the opinion

1. Unless otherwise indicated under this item, this written opinion was drawn up based on the language in which the international application was filed.

[ ] This written opinion is in the following language_____which is:

[ ] the language of a translation furnished for the purposes of the international search (under Rule 12.3 and 23.1(b)).

[ ] the language of publication of the international application (under Rule 12.4).

[ ] the language of a translation furnished for the purposes of the international preliminary examination (under Rule 55.2 and/or 55.3).

2. This opinion has been drawn up on the basis of (Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".):

[ ] the international application as originally filed.

[X] the description: pages 1-29, as originally filed
pages _____, received by the International Preliminary Examining Authority on _____
pages _____, received by the International Preliminary Examining Authority on _____

[X] the claims: Nos. 2-11, 15-23, 25, as originally filed
Nos. _____, as amended under Article 19 PCT
Nos. 1, 12, 13, 14, 24, received by the International Preliminary Examining Authority on 08.04.2005
Nos. _____, received by the International Preliminary Examining Authority on _____

[X] the drawings: ~~pages~~/Figs. 1-4, as originally filed
pages/Figs. _____, received by the International Preliminary Examining Authority on _____
pages/Figs. _____, received by the International Preliminary Examining Authority on _____

[ ] the sequence listing or related table
see supplementary column relating to sequence listing,

3. [ ] The amendments have resulted in the cancellation of:

[ ] the description, page _____
[ ] the claims, Nos. _____
[ ] the drawings, sheets/fig _____
[ ] the sequence listing (specify) _____
[ ] the table relating to sequence listing (specify) _____

4. [ ] This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

[ ] the description, page _____
[ ] the claims, Nos. _____
[ ] the drawings, sheets/fig _____
[ ] the sequence listing (specify) _____
[ ] the table relating to sequence listing (specify) _____

WRITTEN OPINION OF THE INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

Intern. application No.PCT/JP2004/008471

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step, or to be industrially applicable have not been examined in respect of:

☐ the entire international application,
☒ claims Nos. 22 and 23

because:

☒ the said international application, or the said claim No(s). 22 and 23 relate to the following subject matter which does not require an international preliminary examination (specify):

The invention described in claims 22 and 23 is that of a commercial method and an advertising method and consequently falls under methods of business activities. Claims 22 and 23 relates to a subject matter which does not require an international preliminary examination by the International Preliminary Examining Authority under PCT rule 67.1 (iii).

☐ the description, claims or drawings (indicate particular elements below) or said claims Nos. is (are) so unclear that no meaningful opinion could be formed (specify):

☐ the claims or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 22 and 23

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C (guideline for preparing specification etc containing base sequence and/or amino acid sequence) of the Administrative Instructions In that:

the written form
☐ has not been furnished
☐ does not comply with the standard

the computer readable form
☐ has not been furnished
☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ have not been furnished
☐ do not comply with the technical requirements

☐ See separate sheet for further details.

WRITTEN OPINION OF THE INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International application No.
PCT/JP2004/008471

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-11, 24, 25	YES
	Claims	12-21	NO
Inventive Step (IS)	Claims	1-11	YES
	Claims	12-21, 24, 25	NO
Industrial Applicability (IA)	Claims	1-21, 24-25	YES
	Claims		NO

2. Citations and Explanations

Reference 1: CHEST Vol.123, No.5 (May 2003) p.1375-1378

Claims 12-21, 24 and 25

Reference 1 describes use of a monoclonal antibody specific to D-dimer, for the measurement of D-dimer level in patients suspected to have acute aortic dissection.

The reagent described in claims 12-21 is considered to contain an antibody that recognizes D-dimer suitable for the evaluation of the diseases described in each of these claims. On the other hand, a monoclonal antibody specific to the D-dimer described in Reference 1 is the same as the antibody of claims 12-21 as a substance, and is not considered to be a form unsuitable for the evaluation of the diseases described in claims 12-21.

Therefore, the invention relating to claims 12-21 lacks novelty (see PCT international search and international preliminary examination Guideline 5.23).

In addition, use of an antibody for the production of a reagent is expected to be done by those of ordinary skill in the art.

Claims 1-11

Determination of possibility of having developed acute aortic dissection when the measured D-dimer concentration is not less than the blood D-dimer cut-off value pre-established between acute aortic dissection and acute myocardial infarction, and determination of the onset of Stanford type A acute aortic dissection, Stanford type B acute aortic dissection or acute myocardial infarction based on the measurement of the D-dimer concentration are not described in any of the references cited in the International Search Report, nor are they obvious to those of ordinary skill in the art.